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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,114	12/05/2003	Scott A. Burton	59098US002	3162

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
06/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/729,114	BURTON ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-12 and 14-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-12 and 14-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/25/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and IDS, both filed 05/25/2010.

Claims 3, 4, 13, 29, and 30 have been canceled.

Claims 1-2, and 5-12, 14-28 are pending and included in the prosecution.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amount of mineral oils of “at least 60%” as claimed by claims 18 is not disclosed anywhere in the present disclosure. In page 14, lines 1-2, applicant disclosed that: “The plasticizing agent is typically used in amounts of from about 1 to 2000 parts by weight per 100 parts of the hydrophobic polymer." Therefore, applicant disclosed wide range of the amount of plasticizer in relation to 100 parts of the polymer composition, and not “the mineral oil is present in an amount of at least 60 wt%, based on the total weight of the polymer composition. In table 2, page 24, applicant disclosed gel composition comprising 69% KAYDOL (mineral oil). However, this amount is only with 30% D1124K (very specific SIS polymer) and 1% IRGANOX 1010 (specific antioxidant), and this does not form at least 60% of the total weight of the polymer composition that further comprises 1-60% micro particles. Further, the claimed “at least 60%” does not limit the amount of the mineral oils to 2000 parts as disclosed, it can by higher than the disclosed because it does not have an upper limit.

In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Response to Arguments

3. Applicant's arguments filed 05/25/2010 have been fully considered but they are not persuasive. Applicants argue that claims 29 and 30 having been cancelled, these rejections are rendered moot.

In response to this argument, it is argued that canceling claims 29 and 30 does not render moot the rejection of claim 18 that still recite "at least 60%" which is not supported by the original specification and it does not have upper limit.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-2, 5-12, 14-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-8, 11-19, 21-26, 60, 75-78, 82-84, 88-94, 97-101, 103-107 of copending Application No. 10/728,577. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent

granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: wound dressing comprising aperture substrate and polymer composition comprising organic hydrophobic polymeric matrix, hydrophilic microparticles, and plasticizer, claimed by claim 15 of the copending application. The present claims and the conflicting claims of the copending application are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-2, 5-12, 14-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 94, 96-117 of copending Application No. 10/728,439. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: wound dressing comprising polymer composition comprising organic hydrophobic polymeric matrix, hydrophilic microparticles, bioactive agent, and mineral oil plasticizer, claimed by claims 95, 112 and 116 of the copending application. The difference between the present claims and the conflicting claims is that the present claims recite substrate. The substrate is known in the art of wound dressing, and one having ordinary skill in the art would have provided substrate to support the polymer

matrix as evident by claim 117 of the copending application. The present claims and the conflicting claims of the copending application are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. The examiner acknowledged applicant's intention to provide an appropriate response to the double patenting rejection upon an indication of otherwise allowable subject matter and in the event this rejection is maintained. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-2, 5-8, 12, 14-18, 20, 21, and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cilento et al (EP 0512855, IDS filed 03/02/2009) in view of Lykke (WO 02/066087, IDS 05/12/2005).

Applicant Claims

Currently amended claim1 is directed to a wound dressing comprising an apertured liquid permeable substrate and an absorbent, nonadherent polymer composition coated on or impregnated in the substrate; wherein the wound dressing includes substrate apertures that are unobstructed by the polymer composition; and wherein the absorbent, nonadherent polymer composition comprises: a hydrophobic organic polymer matrix; 1 wt-% to 60 wt-% hydrophilic organic microparticles, which when in a nonhydrated form have an average particle size of 10 microns or less; and mineral oil; wherein the polymer matrix, microparticles, and mineral oil are present in the

polymer composition in an amount effective to render the composition sufficiently nonadherent such that when coated on a substrate the nonadherent polymer composition displays a 180° peel strength from stainless steel of less than 1 N/cm.

Currently amended claim 19 further recites that the hydrophobic organic polymer matrix comprises a styrene-isoprene-styrene copolymer, a styrene-butadiene-styrene copolymer, or mixtures thereof; and the hydrophilic microparticles comprising an amine-containing organic polymer.

Currently amended claim 20 further recites that the hydrophobic organic polymer matrix comprising a styrene-isoprene-styrene copolymer, a styrene-butadiene-styrene copolymer, or mixtures thereof; and the hydrophilic microparticles comprising sodium polyacrylate copolymer.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Cilento teaches an absorbent wound composition comprising a wound filler polymeric matrix comprising styrene radial or block type copolymers (i.e., hydrophobic thermoplastic elastomeric polymer) such as styrene-isoprene-styrene (page 3, lines 3-16), 5-40% mineral oil, and 25-75 wt % absorbing powders comprising absorbent polyacrylates which include salts of crosslinked polyacrylic acid and sodium polyacrylate (page 3, lines 37-43). Sodium polyacrylate is disclosed by applicant as the copolymer of sodium acrylate and acrylic acid in the present application page 8, lines 24-25. Powders are dry, i.e. nonhydrated. The reference teaches the polymeric matrix comprises

secondary absorbent powders which read on additional additives claimed by claim 16 (page 10, lines 32-42). The mineral oil functions as a plasticizer for the styrene radial or block copolymer component and also functions to increase the stretchability of the wound filler matrix (page 3, lines 17-18). The absorbent powders can absorb 500-1000% liquid of their original weight, implying that powder is dry (page 10, lines 15-17). Cilento teaches the use antimicrobial agents (page 3, line 48). Cilento teaches a method of wound healing which comprises placing the absorbent wound filler into the wound to absorb the exudates. The wound filler can be removed from the wound in one piece and does not cause wound injury on removal. The wound filler keeps the wound bed moist and produces in a wound an environment suitable for healing (page 2, lines 34-42). The polymer matrix disclosed by the reference is not disclosed as adhesive, rather soft plastic and lightly tacky that does not adhere to the wound (page 3, line 54; page 10, line 20). The wound filler can be covered by 4x4 (page 10, lines 11-12).

With regard to amount of mineral oils as claimed by claim 18, Cilento teaches 5-40% mineral oils and further teaches the advantage of the mineral oils function as a plasticizer for the styrene radial or block copolymer component and also function to increase the stretchability of the wound filler matrix. Therefore, one having ordinary skill in the art would have determined the amount of the mineral oils in the composition according to the desired properties of the polymeric matrix.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Cilento desired to absorb wound exudates and further desired to cover the polymer matrix, however, the reference does not explicitly teach the apertured substrate. Cilento does not explicitly teach the particles size.

Lykke teaches medical article comprising a composition comprising a polymeric matrix and absorbent particles of microcolloid having particle sizes less than 10 microns (abstract; page 3, 7th paragraph; page 7, 1st paragraph; page 11, 3rd paragraph; page 12; page 28, claims 3 and 4), and preferably the particle size less than 1 micron (page 4). The smaller size particles influence the rheological properties of the article and are able to pass through narrow nozzles during production (page 7, 2nd and 3rd paragraphs). The microcolloid particles form from 5-100% by weight of the composition (page 5, 3rd paragraph). The particles are made of acrylic acid polymer (page 15, 1st paragraph; page 16, 4th paragraph). The particles are dry powder, i.e. nonhydrated (page 5, last paragraph). The composition further comprises a plasticizer (page 14, 3rd paragraph; page 18, 2nd paragraph). The polymeric matrix is preferably hydrophobic (page 6, 6th paragraph). The polymer matrix comprises S-EB-S as claimed by claim 25 (polystyrene-polyethylene/butylene-polystyrene), S-I-S and S-B-S copolymers (page 17, 5th paragraph). The composition is coated on porous substrate to form wound dressing that allows the wound exudates to pass through the layer quickly (page 9, 2nd and 3rd paragraphs). The matrix further comprises active agents including antibacterial agents (page 19, 3rd paragraph).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing formed of polymer matrix comprising hydrophobic polymer, hydrophilic particles of polyacrylate and mineral oil plasticizer that can be covered by gauze as taught by Cilento, and further add the porous substrate taught by Lykke to cover the polymer matrix. One would have been motivated to do so because Cilento desired to cover the polymer matrix and to remove wound exudates, and motivated by the teaching of Lykke that porous substrate forms wound dressing that allows the wound exudates to pass through the covering layer quickly. One would reasonably expect formulating wound dressing comprising polymer matrix comprising hydrophobic polymer, hydrophilic particles of polyacrylate and mineral oil plasticizer coated on a porous substrate that allows quickly passage of the wound exudates.

Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound filling polymer matrix comprising hydrophobic polymer, hydrophilic particles of polyacrylate and mineral oil plasticizer as taught by Cilento, and select the particles as small as less than I micron as taught by Lykke. One would have been motivated to do so because Lykke teaches that smaller size particles influence the rheological properties of the wound dressing and are able to pass through narrow nozzles during production. One would reasonably expect formulating wound dressing comprising polymer matrix comprising hydrophobic polymer, hydrophilic

particles of polyacrylate having small sizes and mineral oil plasticizer, wherein the dressing has good rheological properties and easy to produce.

Claims 1 and 20 recite the properties of the composition that would be displayed when the composition is coated on a substrate and the composition of Cilento would also display those characteristic properties when coated on a substrate since Cilento does not teach the polymer matrix as adhesive and comprises the same hydrophobic polymer, hydrophilic particles and mineral oils.

With regard to claims 7 and 8, while Lykke teaches fine pore sizes of the porous substrate, it does not explicitly teach the number of the pores per square cm as claimed by claim 7 or pore size of 1 mm to 0.5 cm as claimed by claim 8. It is the examiner's position that the pore size and their number are result effective variables because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Evidence to support the examiner's position is found in Lykke's reference in page 10, 1st paragraph, where the reference teaches that porosity can be controlled and higher porosity is advantageous.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

12. Claims 9-11, 19, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cilento in view of Lykke as applied to claims 1-2, 5-8, 12, 14-18, 20-21, 23-30 and further in view of the article "SALCARE® SC95" by Ciba®.

The combined teachings of Cilento and Lykke are previously discussed as set forth in this office action.

Although Cilento teaches sodium polyacrylate and Lykke teaches varieties of materials of the microcolloidal particles including acrylic polymers, however, the references do not specifically teach the specific amine-containing polymers forming the microparticles as claimed by claims 9-11, 19, 22.

The article teaches that "SALCARE® SC95" is a cationic homopolymer dispersed in medicinal grade white oil. SALCARE® SC95 does not require pre-mixing or special equipment, has high thickening efficiency, and gives good uniform performance when incorporated in cosmetics.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing comprising porous substrate and polymer composition comprising a hydrophobic polymeric matrix and hydrophilic absorbent particles of acrylic acid polymers as taught by Cilento combined with Lykke, and replace the acrylic acid particles by SALCARE® SC95 particles taught by the article of Ciba®. One would have been motivated to do so because of the article of Ciba® teaches that such material does not require pre-mixing or special equipment, has high thickening efficiency, and gives good uniform performance when incorporated in cosmetics. One would reasonably expect formulating wound dressing comprising

porous substrate and polymer composition comprising a hydrophobic polymeric matrix and absorbent particles made of SALCARE® SC95 that is safe to the skin and easy to produce.

Response to Arguments

13. Applicant's arguments filed 05/25/2010 have been fully considered but they are not persuasive.

Applicants argue that there the combination of Cilento and COLOPLAST (Lykke) does not teach or suggest Applicants' invention. Cilento is directed to a wound filler described as a "doughy mass". The wound filler includes a polymer matrix that is sponge-like or includes a network of polymeric stretchable fibers. The polymeric matrix is a stretchable, elastic, sponge-like network. It is formed into a "flexible sheet or slab". There is no teaching or suggestion that this doughy mass could be coated on or impregnated into an apertured substrate to form a wound dressing, wherein the wound dressing includes substrate apertures that are unobstructed by the polymer composition.

In response to this argument, applicants' attention is directed to the scope of the present claims that is directed to a product, and all the elements of the product are taught by combination of the cited prior art. The polymer matrix taught by Cilento is not non-adherent to the wound, rather soft plastic and lightly tacky (page 3, line 54; page 10, line 20), and can be covered by 4x4 (page 10, lines 11-12). The 4x4 covering, which is apertured gauze material, suggests coating the polymer matrix, or support the matrix

with an apertured substrate. In response to applicants' argument regarding dough material cannot be coated on a substrate without obstructing the apertures of the substrate, it is argued that spreading of the polymer matrix on a substrate or covering by 4x4 gauze does not completely cover the substrate or 4x4, therefore, not all apertures of the substrate are obstructed. The soft tacky dough like polymer matrix can be applied on a substrate in discrete locations, or islands so not obstructed the substrate totally.

Applicants argue that although Cilento discloses the use of mineral oil in combination with particles, the particles are not of the size claimed. Although COLOPLAST mentions the use of mineral oil and microparticles in adhesive compositions, there is no teaching or suggestion of nonadherent compositions including mineral oil and hydrophilic organic microparticles.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further it is noted that applicants themselves admit that Cilento discloses the use of mineral oil in combination with particles and COLOPLAST teaches the use of mineral oil and microparticles wound dressing compositions. Further , the examiner points out to the fact that COLOPLAST teaches preferred particle size less than 1 micron and further teaches that the smaller size particles influence the rheological properties of the article and are able to pass through narrow nozzles during production; and Cilento teaches the

non adherent composition. Therefore, combination of Cilento with COLOPLAST teaches all the elements of the present invention which are wound dressing comprising polymer matrix comprising hydrophobic polymer, hydrophilic particles of polyacrylate having particle sizes of less than 1 micron and mineral oil plasticizer.

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require

absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

Applicants further argue that because the Cilento is directed to a filling material, one of skill in the art would not want to, or need to, coat it on or impregnate it into an apertured substrate.

In response to this argument, it is argued that Cilento desired to cover the polymer matrix filling material with gauze, i.e. apertured substrate, and desired to remove the wound exudates, and COLOPLAST teaches porous substrate, i.e. apertured substrate, that allows the wound exudates to pass through this covering layer quickly. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polymer matrix wound dressing comprising hydrophobic polymer, hydrophilic particles of polyacrylate and mineral oil plasticizer that can be covered with a 4x4 gauze as taught by Cilento, and further add the porous substrate taught by COLOPLAST to cover the polymer matrix of Cilento instead of the 4x4 gauze. One would have been motivated to do so because Cilento desired to remove wound exudates and further desired to cover the polymer matrix filling the wound, and motivated by the teaching of COLOPLAST that porous substrate forms

wound dressing that allows the wound exudates to pass through the covering layer quickly. One would reasonably expect formulating wound dressing comprising polymer matrix comprising hydrophobic polymer, hydrophilic particles of polyacrylate and mineral oil plasticizer coated on a porous substrate that allows quickly passage of the wound exudates.

In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

Applicants argue that Cilento teaches away from such an embodiment: "[G]auze and other fibrous materials have the disadvantage in that when new tissue is formed, in the process of healing, it engulfs the fibers of these materials and it is tom when the material is removed causing wound injury on removal" (see, for example, page 2, lines

12-14). Thus, the purpose of Cilento is to develop a product that is placed directly into a wound and is not coated on or impregnated into a substrate.

In response to this argument, it is pointed out to the teaching of Cilento at page 10, lines 11-12, to cover the polymer matrix wound filling with 4x4 gauze. Therefore, Cilento does not teach away from the present invention. In fact Cilento teaches in the background section the disadvantage of using the gauze or other fibrous materials alone by themselves on the wound because new tissue growth is removed when the fibrous materials are removed, and Cilento has solved this problem by applying the polymer matrix as wound filling materials and cover it with the gauze to overcome this problem. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." In re Gurley, 27 F.3d 551,553 (Fed. Cir. 1994).

With regard to the rejection of the claims 9-11, 19, 22 under 35 U.S.C. 103(a) as being unpatentable over Cilento in view of Lykke as applied to claims 1-2, 5-8, 12, 14-18, 20-21, 23-30 and further in view of the article “SALCARE® SC95” by Ciba®, applicants have failed to traverse the rejection and the response is considered to be

acquiescence to the position taken by the examiner. The rejection is therefore repeated for reasons of record. See MPEP 37 CFR 1.111 (b).

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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